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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,702	01/23/2002	Frank Zocher	50521	8285
26474	7590	05/19/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,702

Applicant(s)

ZOCHER ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004 and 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s)    is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5-8, 11-13, 15, 16 and 18-21 is/are allowed.
- 6) ☒ Claim(s) 4 and 17 is/are rejected.
- 7) ☐ Claim(s)    is/are objected to.
- 8) ☐ Claim(s)    are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No.   .
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>  </u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                 |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>  </u> | 6) <input type="checkbox"/> Other: <u>  </u>  |

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Applicants object to the "Notice of Non-Compliant Amendment" mailed 3/31/04 that stated that marked up versions of the claims are no longer accepted. They argue that marked up versions are required. The examiner fully agrees with applicants' objection. The "Notice of Non-Compliant Amendment" was filled out and signed by a clerical employee who mis-interpreted the rules. The error is regretted.

Claims 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is incorrect in the recitation of "equillibrium" which apparently should be "equilibrium".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claim requires the presence of a particular strain of organism, namely *Streptomyces antibioticus* Tu4. It is not clear that all of the requirements of 37 CFR 1.801-1.809 as to deposit conditions and availability upon issuance of a U.S. patent have been met. Applicant argues that a copy of the deposit receipt is enclosed and that this should overcome the instant rejection. As stated in MPEP 2410.01, "the mere indication that a deposit has been made under condi-

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tions prescribed by the Budapest Treaty would satisfy all conditions of these regulations except the requirement that all restrictions on access be removed on grant of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990)". This assurance may be made by an averment by applicants' attorney.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Lutz-Wahl (AG). The reference teaches the strain of the instant claim in Table 1. This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection.

Applicants allege that the strain *Streptomyces antibioticus* Tu4 mentioned in the instant reference is in a non-public collections without any proof offered whatsoever. This is not probative as to the propriety of the instant rejection. Applicant must offer some proof that the depository listed here in a non-public one and that a scientist could not obtain a copy of this strain. This may be done by a statement from someone of authority at the depository to this effect. Applicants are claiming a particular strain and that strain by that name is listed in a publicly available reference published approximately 9 months before the effective filing date of the appli-

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cation. There must be some convincing probative evidence that this strain was not available to the public before applicants may obtain such a claim.

The previous e5 USC § 102(a) rejection over Zocher, et al. is hereby dropped due to applicants perfecting of their claim to priority. The previous 35 USC § 103(a) rejection over either of Rink, et al. (AD), Zocher, et al. (AH) or Nells, et al. (U) is dropped due to applicants' amendment of claim 7 to include the limitation that the analyte comes from *Streptomyces*.

Claims 1-3, 5-8, 11-13, 15-16 and 18-21 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose

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telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charles E. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
May 14, 2004